

(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to ensure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

§ 72.146 Design control.

(a) The licensee shall establish measures to ensure that applicable regulatory requirements and the design basis, as specified in the license application for those structures, systems, and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to ensure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in

lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to items such as the following: criticality physics, radiation, shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

(c) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license require NRC approval.

§ 72.148 Procurement document control.

The licensee shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by its contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this subpart.

§ 72.150 Instructions, procedures, and drawings.

The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§ 72.152 Document control.

The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and

drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must ensure that changes to documents are reviewed and approved.

§ 72.154 Control of purchased material, equipment, and services.

(a) The licensee shall establish measures to ensure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(b) The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications prior to installation or use of the material and equipment. The licensee shall retain or have available this documentary evidence for the life of ISFSI or MRS. The licensee shall ensure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee or designee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

§ 72.156 Identification and control of materials, parts, and components.

The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must ensure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item as required, throughout fabrication, installation, and use of the item. These identification and control

measures must be designed to prevent the use of incorrect or defective materials, parts, and components.

§ 72.158 Control of special processes.

The licensee shall establish measures to ensure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

§ 72.160 Licensee inspection.

The licensee shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products cannot be carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents.

§ 72.162 Test control.

The licensee shall establish a test program to ensure that all testing required to demonstrate that the structures, systems, and components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the ISFSI or MRS